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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

6751 Steger Drive
Cincinnati, OH 45237-3097

WARNING LETTER

October 14, 1998

Cin-WL-1999-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

K. Chris Chung M.D.
Chief Executive Officer
Wright Health Radiology/NMI
1222 South Patterson Blvd.
Dayton, OH 45402

Dear Dr. Chung:

Your facility was inspected on October 8, 1998 by a representative from the State of Ohio Radiation Control under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> This inspection found that the last medical physicist survey was performed greater than 14 months since the previous survey. The regulation requires a medical physicist survey shall be performed at least annually.

This letter is not intended to be an all-inclusive list of deficiency at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 and regulations under the Act. The specific violation noted in this letter and in the printed summary of test results and inspection observations issued at the close of the inspection may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be deviations from the quality standards, you must promptly initiate permanent corrective actions.

You should take prompt action to correct this deficiency. Failure to promptly correct this deficiency may result in regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil money penalties up to $10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to

comply with the Standards. Continuation of any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in an injunction.

Please notify this office in writing within 15 working days of receipt of this letter. Please describe the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violation. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the noncompliance issue found relates to quality control or other records, please furnish example records (i.e., medical physicist's survey report) showing compliant record keeping. (Patient names or identification should be omitted from any copies submitted).

Your response should be sent to R. Terry Bolen, MQSA Radiological Health Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, OH 45202.

Sincerely yours,

R. Duane Satzger, Ph.D.
Acting District Director
Cincinnati District Office